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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,926	04/16/2001	Peter Pochlauer	2001_0331A	5439

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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,926

Applicant(s)

POCHLAUER ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Current Status

1. This action is responsive to Applicant's amendment of 13 November 2001 in Paper No 4 responsive to the Office Action of 10 August 2001 in Paper No 5.
2. Receipt and entry of Applicant's amendment is acknowledged. The claim objections set forth in paragraphs 1, 2 and 3 are withdrawn in response thereto.
3. Applicant's cancellation of original claims 1-10 and addition of new claims 11-19 is hereby acknowledged. Claims 11-19 remain outstanding.
4. The rejections under 35 USC § 102 set forth in paragraphs 7 and 8 of the previous Office Action and under 35 USC §103 set forth in paragraph 9 of the previous Office Action are withdrawn in favor of the new rejections below.
5. Applicant's remarks have been carefully considered but are moot in view of the withdrawal of the previous rejections.

New Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

6. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites the limitation "(R)-2-chloromandelic acid is employed". This recitation creates confusion since it seems to imply that (R)-2-

chloromandelic acid is a reagent and not the product of the process as would be the case if the limitation read "(R)-2-chloromandelic acid is produced". Claim 14 is thus rendered indefinite.

Claim Rejections - 35 USC § 103

7. Claims 11-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Effenberger et al (US 4,859,784 08-1989) and further in view of Collet et al (Bulletin de la Société Chimique de France 1973, 12, Pt. 2, pages 3330-3334) and further in view of McMasters (Chem2O06 Laboratory 1997, Expt. 1, Part B. Recrystallization and Melting Point Determinations. from world wide web :chemistry.mcmaster.ca/~chem2o6/labmanual/microscale/ms-recrs.html).
- Effenberger discloses (Column 1, line 66- Column 3, line 11) a method for the synthesis of optically active cyanohydrins via the reaction of an aromatic aldehyde with hydrocyanic acid in the presence of the enzyme D-oxynitrilase as a catalyst. Aromatic hydrocarbons (Column 2, lines 52-56) are taught as solvent and the presaturation with water or an aqueous buffer corresponding to the instant co-solvent is also taught (Column 2, line 66- column 3, line 7). The amount of water in the water-saturated aromatic solvent is considered to fall within the limits of instant claim 19. Effenberger specifically teaches (Column 2, line 16) the use of o-chlorobenzaldehyde in the process. This corresponds to the intermediate required for synthesis of 2-chloromandelic acid (cf. instant claim 14). Effenberger exemplifies (Column 3, line 49 – column 4, line 54) the cases of benzaldehyde, o- and m -methoxybenzaldehyde which proceed with

diastereomeric excesses of 99.3, 90 and 98%, respectively, for the crude product cyanohydrins. Effenberger does not teach the process for conversion of the product cyanohydrins into optically active 2-hydroxycarboxylic acids but does specifically suggest (Column 3, lines 15-19) that the crude solutions of cyanohydrins can be directly converted into optically active 2-hydroxycarboxylic acids:

“It is not necessary that the crude solutions be purified or treated any further, but can be directly used in further processes under certain conditions, for instance by hydrolysis into the corresponding optically active 2-hydroxycarboxylic acids.”

Collet, however, discloses (page 3332, right column, last paragraph) a process for the synthesis of optically pure substituted mandelic acids via the acidic hydrolysis of racemic halomandelonitriles at room temperature with stirring for 15 hours followed by extraction from the hydrolysis mixture at room temperature. Collet further discloses (Page 3333, left column, 2nd and 3rd paragraphs from bottom under heading “*Acides (+) and (-) o-chloromandéliques*”) resolution of the racemic o-chloromandelic acids via formation of the diastereomeric salts with (-)-ephedrine, recovery of the free acids from their salts to give optically enriched (R)-o-chloromandelic acids which can then be rendered optically pure by repeated recrystallization from benzene. Collet is silent about the details of the crystallization from benzene. The limitations of instant claim 15, however, describe a conventional recrystallization experiment with times and temperatures

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that one of ordinary skill in the art would ordinarily ascertain in the course of optimizing the crystallization process and which, in the absence of an unexpected result, cannot confer patentability. McMasters teaches (Page 1, first full paragraph) such a conventional process. It would naturally occur to one of ordinary skill in the art to combine the method for the production of optically active mandelonitriles taught by Effenberger with Collet's process of hydrolysis of mandelonitriles to generate the corresponding mandelic acids (2-hydroxycarboxylic acids). Such a combination results in nearly optically pure mandelic acids after extraction of the hydrolysis mixture. Effenberger in fact suggests a combination of such processes. It is also obvious to use recrystallization from benzene as disclosed by Collet to give optically pure (R)-2-chloromandelic acid from the optically enriched material. Thus it would have been obvious for one of ordinary skill in the art to have performed this invention at the time applicant asserts it was made. The motivation would have been to use the method of Effenberger and Collet to produce optically pure 2-hydroxycarboxylic acids which are important as pharmaceuticals and as intermediates for the synthesis of pharmaceuticals. Since both references are drawn to the production of the same ultimate products and specifically teach the necessary elements the expectation for success would be extraordinarily high.

Conclusion

8. Claims 11-19 are outstanding. Claims 11-19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on 703-308-1701. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

PAZ
January 25, 2002



GARY GEIST
SUPERVISORY PATENT EXAMINER
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